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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|----------------------|------------------|
| 09/655,815 | 09/06/2000 | Robert Lanza | P 0275705 23523-0162 | 8460 |

7590 12/13/2001

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[REDACTED] EXAMINER

TON, THAIAN N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1632 | 7 |

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/655,815 | LANZA ET AL. | |

| | | |
|-----------------|-----------------|--|
| Examiner | Art Unit | |
| Thaian N. Ton | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 20-28, 33, and 38-48, drawn to a method of testing the immune compatibility of cloned cells or tissues in an animal model, a method of providing a patient in need of a transplant with an immune-compatible transplant, an animal containing at least one teratoma, and teratomas classified in class 424, subclasses 9.2, 93.21, class 800, subclasses 3, 8, 9, 11, 13, 18, class 514, subclass 44 for example.
- II. Claims 15-19, 29-32, 34-51, drawn to a method of generating immune compatible tissue for transplantation, a stable graft comprised of isogenic nuclear DNA and allogeneic mitochondrial DNA, an animal containing at least one teratoma, and teratomas, classified in class 424, subclass 93.21, class 800, subclasses 3, 8, 9, 11, 13, 18, class 514, subclass 44 for example.
- III. Claims 52 and 53, drawn to methods of identifying mitochondrial histocompatibility antigens using cross-species nuclear transfer, classified in class 435, subclass 7.1, for example.
- IV. Claim 54, drawn to antibodies, classified in class 530, subclass 387.1, for example.
- V. Claim 55, drawn to lymphocytes, classified in class 435, subclass 325+, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I and either of Inventions II or III are mutually exclusive and independent methods. The method of testing immune compatibility of Invention I is not required for the implementation of the method of generating immune compatible tissue of Invention II, or the method of identifying mitochondrial histocompatibility antigens of

Invention III, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention I and either of Invention IV or V are mutually exclusive and independent. The method of testing immune compatibility of Invention I is not required for the implementation of the antibodies of Invention IV, or the lymphocytes of Invention V, and vice versa.

Invention II and Invention III are mutually exclusive and independent methods. The method of generating immune compatible tissue of Invention II is not required for the implementation of the method of identifying mitochondrial histocompatibility antigens of Invention III, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention II and either of Inventions IV or V are mutually exclusive and independent. The method of generating immune compatible tissue of Invention II is not required for the implementation of the antibodies of Invention IV, or the lymphocytes of Invention V, and vice versa.

Invention III and either of Inventions IV or V are mutually exclusive and independent. The method of identifying mitochondrial histocompatibility antigens of Invention III is not required for the implementation of the antibodies of Invention IV, or the lymphocytes of Invention V, and vice versa.

Inventions IV and V are to distinct products. The antibodies of Invention IV can be used in immunological assays and the lymphocytes of Invention V can be used for measuring immune response.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Karen Hauda, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-6608. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

TNT

Thaian N. Ton
Patent Examiner
Group 1632

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1600/1630